



Food and Drug Administration Minneapolis District 240 Hennepin Avenue Minneapolis MN 55401-1999 Telephone: 612-334-4100

March 9, 2001

WARNING LETTER

CERTIFIED MAIL RETURN RECEIPT REQUESTED

Refer to MIN 01 - 40

Michael Otten
President
Century Foods International Inc.
400 Century Court
Sparta, Wisconsin 54656

Dear Mr. Otten:

An inspection of your acidified food processing facilities at 400 Century Court and 920 Industrial Drive, Sparta, WI, was conducted by Investigator William Keer of the Food and Drug Administration (FDA) on September 6 and 11, 2000. The inspection targeted your production of acidified dairy products contained in hermetically sealed aerosol cans:

Sour Cream Cream Cheese Spread Strawberry Cream Cheese Spread Onion and Chive Cream Cheese Spread

The identification of your aerosol sour cream (e.g. NULV) Sour Cream) as "Sour Cream" with the claim "REAL SOUR CREAM" causes the product to be misbranded under Section 403(g) and 403(a) of the Federal Food, Drug and Cosmetic Act because this product is not sour cream, a standardized food (see Title 21, Code of Federal Regulations, Part 131.160[21 CFR 131.160]). The formulation that you provided to our investigator and the affidavit that you signed indicates that the product you identify as "sour cream" and claim as "real sour cream" is actually made from cream cheese, sugar, glucono-delta-lactone, and sorbic acid. The label also falsely includes "sour cream (...)" in the ingredient statement and fails to include the cream cheese ingredients in the statement.

The above violations are not intended to be an all-inclusive listing of the violations associated with your acidified food production facilities. As the firm's president

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you are responsible for ensuring that your production meets all federal, state and local requirements.

Please respond in writing within 15 working days of receipt of this letter detailing the actions you have taken to correct these violations and to prevent their recurrence in the future. If you cannot implement all corrective actions within 15 working days, please include your reasoning for the delays. You may wish to include documentation of your corrective actions in your response to better enable the FDA to determine your compliance status.

You should take prompt corrective actions to prevent the recurrence of these violations. Failure to do so may result in legal action against you and your firm, such as product seizure, injunctive relief, etc.

Your response to this letter and any questions you may have regarding this matter may be directed to Compliance Officer Thomas P. Nelson at the address indicated on the letterhead.

Sincerely,

David R. Yost

Acting Director Minneapolis District

TPN/ccl